

§ 37.45

42 CFR Ch. I (10–1–13 Edition)

(h) In conducting medical examinations pursuant to this Part, physicians and radiographic facilities must maintain the results and analysis of these examinations (including any hard copies or digital files containing individual data, interpretations, and images) consistent with applicable statutes and regulations governing the treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR Part 160 and Subparts A, C, and E of Part 164).

[77 FR 56732, Sept. 13, 2012]

§ 37.45 Protection against radiation emitted by radiographic equipment.

Except as otherwise specified in § 37.41 and § 37.42, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used, must conform to applicable State or Territorial and Federal regulations. Where no applicable regulations exist, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used must conform to the recommendations in NCRP Report No. 102, NCRP Report No. 105, and NCRP Report No. 147 (incorporated by reference, see § 37.10).

[77 FR 56733, Sept. 13, 2012]

SPECIFICATIONS FOR INTERPRETATION, CLASSIFICATION, AND SUBMISSION OF CHEST RADIOGRAPHS

§ 37.50 Interpreting and classifying chest radiographs—film.

(a) Chest radiographs must be interpreted and classified in accordance with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Chest radiograph interpretations and classifications must be recorded on a paper or electronic Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

(b) Radiographs must be interpreted and classified only by a physician who reads chest radiographs in the normal course of practice and who has demonstrated proficiency in classifying the pneumoconioses in accordance with § 37.52.

(1) Initial clinical interpretations and notification of findings other than pneumoconiosis under § 37.50(a) must be provided by a qualified physician who has all required licensure and privileges, and interprets chest radiographs in the normal course of practice.

(2) [Reserved]

(c) All interpreters, whenever interpreting chest radiographs made under the Act, must have immediately available for reference a complete set of the standard radiographs for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10).

(d) In all view boxes used for making interpretations:

(1) Fluorescent lamps must be simultaneously replaced with new lamps at 6-month intervals;

(2) All the fluorescent lamps in a panel of boxes must have identical manufacturer's ratings as to intensity and color;

(3) The glass, internal reflective surfaces, and the lamps must be kept clean;

(4) The unit must be so situated as to minimize front surface glare.

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§ 37.51 Interpreting and classifying chest radiographs—digital radiography systems.

(a) For each chest radiograph obtained at an approved facility using a digital radiography system, a qualified and licensed physician who reads chest radiographs in the normal course of practice must provide an initial clinical interpretation and notification, as specified in § 37.54, of any significant abnormal findings other than pneumoconiosis.

(b) Chest radiographs must be classified for pneumoconiosis by physician readers who have demonstrated ongoing proficiency, as specified in § 37.52(b), in classifying the pneumoconioses in a manner consistent with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Chest radiograph interpretations and classifications must be recorded on a paper or electronic Roentgenographic

Interpretation Form (Form CDC/NIOSH (M)2.8).

(c) All interpreters, whenever classifying digitally-acquired chest radiographs made under the Act, must have immediately available for reference a complete set of NIOSH-approved standard digital chest radiographic images provided for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see §37.10). Only NIOSH-approved standard digital images may be used for classifying digital chest images for pneumoconiosis. Modification of the appearance of the standard images using software tools is not permitted.

(d) Viewing systems should enable readers to display the coal miner's chest image at the full resolution of the image acquisition system, side-by-side with the selected NIOSH-approved standard images for comparison.

(1)(i) Image display devices must be flat panel monitors displaying at least 3 MP at 10 bit depth. Image displays and associated graphics cards must meet the calibration and other specifications of the Digital Imaging and Communications in Medicine (DICOM) P=56734 standard PS 3.14-2011 (incorporated by reference, see §37.10).

(ii) Image displays and associated graphics cards must not deviate by more than 10 percent from the grayscale standard display function (GSDF) when assessed according to the AAPM On-Line Report No. 03, pages 1-146 (incorporated by reference, see §37.10).

(2) Display system luminance (maximum and ratio), relative noise, linearity, modulation transfer function (MTF), frequency, and glare should meet or exceed recommendations listed in AAPM On-Line Report No. 03, pages 1-146 (incorporated by reference, see §37.10). Viewing displays must have a maximum luminance of at least 171 cd/m², a ratio of maximum luminance to minimum luminance of at least 250, and a glare ratio greater than 400. The contribution of ambient light reflected from the display surface, after light sources have been minimized, must be included in luminance measurements.

(3) Displays must be situated so as to minimize front surface glare. Readers must minimize reflected light from ambient sources during the performance of classifications.

(4) Measurements of the width and length of pleural shadows and the diameter of opacities must be taken using calibrated software measuring tools. If permitted by the viewing software, a record must be made of the presentation state(s), including any noise reduction and edge enhancement or restoration functions that were used in performing the classification, including any annotations and measurements.

(e) Quality control procedures for devices used to display chest images for classification must comply with the recommendations of the American Association of Physicists in Medicine AAPM On-Line Report No. 03, pages 1-146 (incorporated by reference, see §37.10).

(1) If automatic quality assurance systems are used, visual inspection must be performed using one or more test patterns recommended by the medical physicist every 6 months, or more frequently, to check for defects that automatic systems may not detect.

(2) [Reserved]

(f) Classification of CR and DR digitally-acquired chest radiographs under this Part must be performed based on the viewing of images displayed as soft copies using the viewing workstations specified in this section. Classification of radiographs must not be based on the viewing of hard copy printed transparencies of images that were digitally-acquired.

(g) The classification of chest radiographs based on digitized copies of chest radiographs that were originally acquired using film-screen techniques is not permissible under this part.

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§37.52 Proficiency in the use of systems for classifying the pneumoconioses.

(a) First or A Readers:

(1) Approval as an A Reader must continue if established prior to October 15, 2012.